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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,242	11/29/2005	Sebastien Huron	2002.022 US	4632
	7590 12/16/200 ng-Plough Animal Hea	EXAMINER		
PATENT DEPARTMENT PO BOX 318 29160 Intervet Lane MILLSBORO, DE 19966-0318			PALENIK, JEFFREY T	
			ART UNIT	PAPER NUMBER
			1615	
			MAIL DATE	DELIVERY MODE
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# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		Application No.	Applicant(s)			
Office Action Summary		10/524,242	HURON ET AL.			
		Examiner	Art Unit			
		Jeffrey T. Palenik	1615			
Period fo	The MAILING DATE of this communication app or Reply	pears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) 又	Responsive to communication(s) filed on <u>06 A</u>	uaust 2008				
·	This action is <b>FINAL</b> . 2b) ☐ This action is non-final.					
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
٠,١	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Dispositi	on of Claims					
· · ·	Claim(s) <u>1-5,7,8 and 18-22</u> is/are pending in th	ne application				
	4a) Of the above claim(s) is/are withdrawn from consideration.					
	5) Claim(s) is/are allowed.					
	6)⊠ Claim(s) <u>1-5,7,8 and 18-22</u> is/are rejected.					
· ·	Claim(s) is/are objected to.					
•	Claim(s) are subject to restriction and/o	or election requirement.				
		, closuch roquirement.				
	on Papers					
•	The specification is objected to by the Examine					
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority ι	ınder 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
2) 🔲 Notic 3) 🔯 Infori	t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date <u>6 Aug. 2008, 10 Feb. 2005 and 15 Oct. 2</u>	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 2007. 6) Other:	ate			



Application No.

### **DETAILED ACTION**

Receipt is acknowledged of Applicants' Amendments and Remarks filed 6 August 2008.

The Examiner acknowledges the following:

The Examiner thanks Applicants for pointing out the typographical error in the opening comments to the preceding Office Correspondence. Applicants are correct that claim 18 has not been withdrawn from consideration, that it remains under consideration, and that it stands as "currently amended".

New claims 19-22 have been added with support. No new claims have been cancelled.

Claims 9, 10 and 12-17 were previously withdrawn from consideration currently remain so. The Examiner notes that despite having been withdrawn from consideration, claims 9, 12-15 and 17 have been addressed in view of the art applied and amended. It should be noted that none of the remarks herein are directed towards the non-elected subject matter.

Additionally, claims 1, 8 and 18 have been amended. Where support for the amendments was not expressly provided, it was found either within Applicants' disclosure and/or originally filed claims. The Examiner acknowledges that no new matter has been added to the claims.

Thus, claims 1-5, 7, 8 and 18-22 now represent all claims currently under consideration.

## INFORMATION DISCLOSURE STATEMENT

One new Information Disclosure Statement (IDS), filed 6 August 2008, is acknowledged and has been reviewed.

Regarding the previously two IDS forms submitted 10 February 2005 and 15 October 2007, despite having been considered for the previous action neither forms were signed or dated

by the Examiner. This has been rectified. Furthermore, it is no longer required that every single entry be initialed by the Examiner, rather the statement "All references considered except where lined through" is annotated into each IDS.

### WITHDRAWN OBJECTIONS/REJECTIONS

# Objection to the Specification

Applicants' amendment to the tradename TENOX® in Applicants' disclosure, renders moot the objection. Thus, said objection has been withdrawn.

# Rejections under 35 USC 112

Applicants' amendments removing the "about" limitations from claim 18, render moot the new matter/written description rejection to claim 18, under 35 USC 112, first paragraph.

Thus, said rejection has been withdrawn.

Applicants' amendment removing the limitation requiring an antioxidant in the formulation of claim 18, as well as making claim 18 an independent claim, renders moot the enablement rejection to claim 18, under 35 USC 112, first paragraph. Thus, said rejection has been **withdrawn**.

Applicants' amendment to claim 18 making it an independent compositional claim rather than being dependent from claim 1, renders moot the lack of antecedent basis rejection to claim 18, 2, 8 and 9, under 35 USC 112, second paragraph. Thus, said rejections have been withdrawn.

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# Rejection under Provisional Nonstatutory Double Patenting

Applicants' amendments to the instant claims, namely claims 8, as well as the copending claims 2-5, render moot the present rejection on the grounds of provisional nonstatutory obviousness-type double patenting over co-pending application number 11/100,982 (US Pre-Grant Publication N° 2005/0226908). Thus, said rejection has been withdrawn.

#### MAINTAINED REJECTIONS/OBJECTIONS

The following rejections are maintained from the previous Office Action dated 1 February 2008:

#### SPECIFICATION

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns,"

"The disclosure defined by this invention," "The disclosure describes," etc.

### RESPONSE TO REMARKS

Applicants' remarks with regard to the objection of the Abstract of the Invention, have been fully considered, but are not persuasive.

Applicants alleges that the Abstract complies with the Patent Office's rules.

In response, the Examiner respectfully directs Applicant to the highlighted portions above as well as MPEP \$608.01(b) and 37 CFR 1.72 .

Thus, for these reasons, Applicants' remarks are found unpersuasive. The above objection is hereby maintained.

## CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7, 8 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christensen (United States Pre-Grant Publication 2001/0036464) in view of Monte (USPN 5,578,336) and Miller (USPN 5,439,924).

The instant claim 1 is drawn to a soft chew pharmaceutical formulation comprising percent a flavoring, a starch, a sugar, an oil and a first additive comprising an active ingredient and their percentage ranges including percentage of moisture. The term "moisture content" as recited in the instant claim 1, is interpreted broadly by the Examiner to mean percentage of water present in the formulation. Furthermore, the recitations "formed by knockout" and "is not an extrudate" in claim 1 are considered by the Examiner to be process limitations which hold no patentable weight with regards to the claimed composition (MPEP 2113). Dependent claim 2 is drawn to a composition which further comprises no greater than 3% of a stabilizer. Dependent claim 3 is drawn to a composition which further comprises no greater than 40% of an emulsifier. Dependent claims 4 and 5 are drawn to compositions which further comprise a second and third additive, respectively, each of which may be in the form of a pharmaceutical, neutraceutical,

vitamin or mineral. Dependent claim 7 is drawn to a composition which further comprises a particular flavor such as fruit, vegetable or artificial flavorings. Dependent claim 8 further limits the active additive ingredient to a particular active agent such as aspirin, ivermectin or praziquantel. Dependent claim 18 is drawn to a composition which recites specific components for the constituents recited in claim 1 and further claims a stabilizer, an emulsifier and an antioxidant and their percentages.

Christensen teaches a soft chewable oral delivery composition which contains one or more active ingredients (0.1-5%) as well as 10-50% starch, 0-40% oil, 5-25% sugar, and 5-20% water ([0006], [0028] and claim 1). Active ingredients taught include pharmaceuticals such as ivermectin, fenbendazole, penicillin, aspirin, and also include vitamins and minerals ([0017] and Example 3). Minor amounts of stabilizers, emulsifiers and flavorants are taught [0017]. Example 5 teaches the use of cherry flavoring (0.1%). Corn starch, soybean oil and sucrose are also taught ([0010], [0012] and [0014], respectively).

Christensen lacks teachings for: 1.) an antioxidant, 2.) the specific stabilizer, emulsifiers or flavorant of claim 18, and 3.) any of the recited percentages of claims 3 and 18.

Monte teaches soft candy confectionaries whose moisture content is 1-95% by weight of water (Abstract; col. 19, lines 51-53). Flavoring, emulsifiers (e.g. Glycerine and Tween-80), an antioxidant (e.g. Vitamin E) and multiple active ingredients (e.g. Vitamin A, niacinamide and pantothenic acid) are also taught as part of the compositions (Tables I and II). Starch, fructose and peppermint oil are also taught in Table I. Fructose is taught as a sugar-based flavoring agent and peppermint oil is taught as an oil-based flavoring agent.

Monte also lacks teachings for 1.) the specific stabilizer, emulsifiers or flavorant of claim 18, and 2.) any of the recited percentages of claims 3 and 18.

Miller teaches chewable tablet oral dose forms (col. 6, lines 3-6) as well as soft and inherently, chewable gelatin capsules (col. 10, lines 35-40) which may contain one or more active agents including ivermectin and ivermectin derivatives (col. 6, lines 26-31). Examples 1 and 2, for example, teach a chewable tablet formulations which further include excipients such as sugar, starch, emulsifiers (e.g. PEG<sub>6000</sub>), and stabilizers (e.g. magnesium stearate). Additional excipients which may be included in Miller's formulations include antioxidants, flavorings, and oils (col. 10, lines 1-5).

In view of the combined teachings of the prior art, one of ordinary skill in the pharmaceutical art would have been motivated to prepare a soft-chew pharmaceutical composition containing the active agents and additives as instantly claimed with a reasonable expectation of success since such a composition and the ingredients for the same are seen to be taught in the prior art. Such would have been obvious in the absence of evidence to the contrary since both Christensen and Monte teach chewable embodiments which comprise multiple overlapping pharmaceutically active agents and additives. Similarly, Christensen and Miller both teach chewable compositions which contain common active agents such as ivermectin and common additive components such as oils, sugars, starch, emulsifiers and stabilizers.

None of the references specifically teach PEG<sub>3350</sub> (e.g. emulsifier) or a sweet apple and molasses flavoring, or any of the recited percentages as claimed by the Applicants. Since the values of each parameter with respect to the claimed composition are adjustable, it follows that

each is a result-effective parameter that a person having ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill, for example, to adjust the type and amount flavoring or to adjust the type and amount of emulsifier (e.g. PEG<sub>3350</sub> versus PEG<sub>6000</sub>) in order to best achieve the most appealing chewable formulation to for the intended end-user. Thus, absent some demonstration of unexpected results from the claimed parameters, optimization of any of these parameters would have been obvious at the time of Applicant's invention.

#### RESPONSE TO ARGUMENTS

Applicants' arguments with regard to the rejection of clams 1-5, 7, 8 and 18 under 103 over Christensen in view of Monte and Miller have been fully considered but they are not persuasive.

Applicants allege, specifically with regards to claim 1, that none of "the cited references teach, suggest or provide motivation for a *knockout* formulation" [emphasis added].

In response, the Examiner respectfully maintains that the amendments made to both claims 1 and 18, wherein it is recited that the claimed formulations "comprise a knockout formulation" and "not an extrudate" continue to be interpreted by the Examiner as product-by-process limitations (MPEP §2113). Furthermore, Applicants' arguments that the references fail to show certain features of Applicants' invention, it is noted that the features upon which applicant relies (i.e., knockout formulation characteristics) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification

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are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

For these reasons, Applicants' arguments are found unpersuasive. Said rejection is therefore maintained.

## **New Rejections**

In light of Applicants' amendments, most notably to claims 1, 8 and 18, as well as the addition of new claims 19-22, the following rejections have been newly added:

## **DOUBLE PATENTING**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4, 5, 7, 8 and 19-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-6 and 19 of copending

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Application No. 11/100,982. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '982 co-pending application are obvious variants, if not anticipatory, of the currently presented claims. The instant claims are obvious variants to those which are co-claimed in so much as the instant claims 1, 4, 5, 8, and 19-21 read on and render obvious independent claim 6 and claims 2, 3, 5, 6 and 19 of the '982 application since the conflicting claims are directed to a method of treating (i.e. using) through administration of a soft chew composition which comprises the three additives: ivermectin, fenbendazole and praziquantel. The instant claims, on the other hand recite the orally administered soft chew composition comprising the same three actives. That the intended use of the instant composition matches that of the method of using the co-pending composition eliminates the statutory distinction between the two applications. Instant claim 1 and co-pending dependent claim 2 recite the same excipient components (i.e. flavoring, starch, sugar and oil), each of which encompass the same ranges. Co-pending independent claim 6 and dependent claims 2 and 19 also read on and render obvious the instant independent claim 18 since the composition recited in claim 18 comprises the additive ivermectin and the percentages of excipients anticipate the ranges of the recited co-pending ranges. Lastly, the flavoring limitations of claim 7 (instant claims) and claim 4 ('982) fully encompass one another.

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This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

# CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, 5, 7, 8 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christensen (United States Pre-Grant Publication 2001/0036464) in view of Kalbe et al. (USPN 6,503,536).

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The instantly amended claim 1 is drawn to a soft chew pharmaceutical formulation comprising a flavoring, a starch, a sugar, an oil and a first additive comprising ivermectin and their percentage ranges including percentage of moisture, which is less than about 15%, as discussed above. Also as discussed above, claim 8 now depends from claim 4 and recites compounds which may comprise the second additive. New claim 19 further limits said second additive to fenbendazole. New claims 20 and 21 further limit the recited third additive of claim 5 to praziquantel. New claim 22 recites the composition of claim 1 as comprising no water.

The teachings to Christensen et al. are discussed above. Christensen expressly teaches the amended moisture content limitation wherein the composition comprises less than 15% moisture, particularly since it teaches said composition as comprising about 10% water (claim 13). Christensen, also as discussed above, is silent to any teachings of an emulsifier, which is to say it comprises 0%. This reads on the limitation of claim 3, which recites that the composition further comprises an emulsifier at a concentration of no more than 40%. Said recited limitation is interpreted by the Examiner as 40% or less, thereby including 0% emulsifier.

Despite the teachings provided, Christensen does not expressly teach the anthelmintic compound praziquantel as a third additive and does not expressly teach the absence of water.

Kalbe et al. teach orally administered granules of hexahydropyrazine derivatives by mixing the active compound in the presence of suitable solvents with hydrophobic carriers and in the presence of auxiliary components to form ready-to-use forms (Abstract). Said hexahydropyrazine derivatives include praziquantel (col. 1, lines 58-63). Further anthelmintically active compounds such as ivermectin and fenbendazole may be added to the granular preparation (col. 2, lines 10-19). Auxiliary components which are taught as part of the

granular preparations include stabilizers, lubricants such as magnesium stearate and binders such as starch (col. 2, lines 44-50) and/or binders such as vegetable, animal or synthetic oils (col. 3, lines 24-25). The granules are further taught as being prepared into a soft chew (i.e. soft gelatin capsule) formulation (col. 3, lines 30-33). Said preparations are taught as being intended for treating animals such as cats and dogs (col. 3, lines 47-50). Though Kalbe does not expressly teach the property of moisture content for the preparation, (i.e. moisture content less than 15%), Kalbe does expressly teach that the dry-mixed composition can be prepared with a solvent other than water (col. 3, lines 3-9). Thus, it is the composition may be prepared comprising no water as instantly claimed.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a soft, orally-administered composition comprising the three instantly claimed additives and auxiliary components in the absence of moisture (i.e. water) as taught and as suggested by the combination of Christensen and Kalbe, modify the amounts of the components, and produce the instantly claimed composition.

One of ordinary skill in the art would have been motivated to do this because Christensen expressly teaches semi-moist oral delivery systems comprising the claimed excipients and their percent ranges as evidenced by the Table in §[0006] and further teaches that the composition prescription drugs such as ivermectin and fenbendazole §[0017]. The teachings to Kalbe reconcile the deficiencies of Christensen by teaching additional anthelmintic pharmaceutical drug embodiments as well as expressly suggesting their combined use (col. 3, lines 10-13). Furthermore, where Christensen teaches "moisturizing" the dry-mixed ingredients using a

combination of solvents which includes as low as 5% water mixed with polyhydric alcohols (claim 1), Kalbe teaches that suitable solvents such as polyhydric alcohols and other organic solvents maybe used in lieu of water to wet the dry granular mixture for compaction into its final, chewable form. Thus, the skilled artisan would have been highly motivated to combine the practiced inventions of Christensen and Kalbe in view of the overlapping technology, namely establishing soft formulations comprising multiple anthelmintic drug compounds, which are administered for the treatment and maintenance of worms in household pets such as cats and dogs.

Since both of the inventions to Christensen and Kalbe overlap in their teachings, as discussed above, one of ordinary skill in the art would have been particularly motivated to prepare the instantly claimed soft-chew administration form. Thus, it would have been *prima facie* obvious to combine the teachings, each of which are taught by the art as being useful for the same purpose, in order to form a third composition, such as that which is instantly claimed, to be used for the very same purpose; the idea of combining them flowing logically from their having been individually taught in the prior art (MPEP §2144.06). *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPO 1069, 1072 (CCPA 1980)

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

All claims have been rejected; no claims are allowed.

#### CONCLUSION

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

#### CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/ Examiner, Art Unit 1615 /MP WOODWARD/ Supervisory Patent Examiner, Art Unit 1615